

REMARKS/ARGUMENTS

Claims 20, 67 and 72-85 are pending in the present application. Claims 20, 67 and 72-85 were examined and rejected. Claims 20, 67, 74, 76-79, 81-84 have been amended. No new matter has been added. Reexamination and reconsideration of the claims as amended, are respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 20, 67, 72-82, 84 and 85 were rejected as being anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,165,183 to Kuehn et al. (Kuehn). The rejection is traversed in part and overcome in part for at least the following reasons.

Claim 20 recites in part a pair of articulating arms that are movable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together. The Examiner characterized Fig. 20 of Kuehn as disclosing this. Applicants respectfully disagree with this characterization of Fig. 20. In Fig. 20, Kuehn discloses a pair of graspers 440 used to grasp valve leaflets (col. 9, lines 49-50). As shaft 456 is pulled, graspers 440 are drawn toward plunger 446. (col. 9, lines 57-59). The graspers do not move closer together, they only move linearly along a slot. Therefore, the graspers 440 in Kuehn are linearly movable but Kuehn fails to teach or suggest that the graspers are movable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together.

Additionally, claim 20 recites in part that the central member is detachable from the shaft while the shaft is in the patient's body. In the Office Action, the Examiner indicated that the entire device in Kuehn may be disassembled. While the device in Kuehn could feasibly be disassembled, one of ordinary skill in the art would not disassemble the device since this would render the device inoperative for its intended purpose as well as potentially endangering the patient. Furthermore, one could not disassemble the device in Kuehn since claim 20 requires that the central member be detached from the shaft while the shaft is in the patient's body. Kuehn neither teaches or suggests how this could be achieved, nor would one of ordinary skill in

the art perform this action since Kuehn's graspers are either in the heart or vascular system and thus there is no way to access the device to disassemble it. For this reason, Kuehn fails to teach or suggest a central member detachable from the shaft while the shaft is in the patient's body.

Moreover, claim 20 also recites in part that the articulating arms are movably coupled to the central member and implantable in the patient's body to maintain the leaflets in the coapted configuration after the shaft has been removed from the patient's body. Kuehn also fails to teach or suggest that graspers 440 are implantable in the patient's body to maintain the leaflets in the coapted position after the shaft has been removed from the patient's body. Kuehn discloses that gripper 438 includes graspers 440 used to grasp each leaflet (col. 9, lines 49-50). Kuehn further discloses that "[a]fter leaflets 122, 124 are fastened, graspers 440 can be released by extending shaft 456 such that gripper 438 can be withdrawn" (col. 9, line 67 - col. 10, line 2). Kuehn clearly distinguishes between grippers which are not left in the body and fasteners which are implanted (col. 9, lines 46-49). Thus, Kuehn's gripper 438 is temporarily placed in the patient's body, but it is removed after the leaflets are fixed. Hence, Kuehn fails to teach or suggest articulating arms that are movably coupled to the central member and implantable in the patient's body to maintain the leaflets in the coapted configuration after the shaft has been removed from the patient's body.

Furthermore, claim 20 recites in part a pair of superior elements that are resiliently biased into an extended configuration. While Kuehn discloses a pair of arms 450, 452 coupled with plunger 446, and Kuehn discloses moving the plunger 446 (col. 9, lines 50-51 and col. 9, lines 60-61.), Kuehn fails to teach or suggest that arms 450, 452 are resiliently biased into an extended configuration.

Nevertheless, in order to more clearly emphasize these differences, claim 20 has been amended to recite an apparatus for repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising:

a catheter shaft having a proximal end and a distal end;

a pair of articulating arms coupled together and forming an angle therebetween, the articulating arms movable from an open position in which portions of the articulating arms are spaced apart with a first angle therebetween, to a closed position in which the portions of the articulating arms are closer together with a second angle therebetween less than the first angle, and to positions between the open position and the closed position, the pair of articulating arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other;

a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the pair of articulating arms can be closed thereby reducing the angle therebetween, to engage the leaflets and thereafter be opened to allow release of the leaflets;

a central member coupled to the catheter shaft near the distal end, the catheter shaft adapted for delivering the pair of articulating arms into a heart, the central member being detachable from the catheter shaft while the catheter shaft is in the patient's body, and the pair of articulating arms being movably coupled to the central member and left in the patient's body while maintaining the leaflets in the coapted configuration after the catheter shaft has been removed from the patient's body; and

a pair of superior elements movably coupled to the central member, the superior elements being configured to engage the superior surfaces whereby the leaflets may be pinched between the articulating arms and the superior elements and wherein the superior elements are resiliently biased into an extended configuration in which portions of the superior elements are spaced apart from the central member for engaging the superior surfaces of the leaflets.

Support for this amendment may be found in Figs. 86 and 87A-87C as well as the corresponding detailed description as filed, therefore no new matter has been added. Kuehn fails to teach or suggest each and every limitation of amended claim 20.

Claim 20 now recites in part a pair of articulating arms coupled together and forming an angle therebetween, the articulating arms movable from an open position in which portions of the articulating arms are spaced apart with a first angle therebetween, to a closed

position in which the portions of the articulating arms are closer together with a second angle therebetween less than the first angle, and to positions between the open position and the closed position. Kuehn's graspers 440 in Fig. 20 are moved by pulling plunger 446, thereby linearly moving graspers 440, however, Kuehn fails to teach or suggest that the angle of the graspers is adjustable. Thus, Kuehn fails to teach or suggest that the graspers 440 are movable to a closed position in which the portions of the articulating arms are closer together with a second angle therebetween less than the first angle. Kuehn also fails to teach or suggest moving graspers 440 to positions between the open position and the closed position. This concept is further emphasized in claim 20 which now recites in part a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the pair of articulating arms can be closed thereby reducing the angle therebetween, to engage the leaflets and thereafter be opened to allow release of the leaflets. As previously discussed, graspers 440 in Kuehn move with plunger 446, but Kuehn fails to teach or suggest that the angle between graspers 440 can be closed thereby reducing the angle therebetween.

Claim 20 also now recites a central member coupled to the catheter shaft near the distal end, the catheter shaft adapted for delivering the pair of articulating arms into a heart, the central member being detachable from the catheter shaft while the catheter shaft is in the patient's body, and the pair of articulating arms being movably coupled to the central member and left in the patient's body while maintaining the leaflets in the coapted configuration after the catheter shaft has been removed from the patient's body. As previously discussed, Kuehn's gripper 438 is used to grasp valve leaflets until the leaflets are fastened (col. 9, line 67 - col. 10 line 1) with a separate fastener. After the fastener is applied to the leaflets, Kuehn's gripper 438 is released from the leaflets and withdrawn (col. 10, lines 1-2). Thus, Kuehn's gripper in Fig. 20 is not left in the patient's body while maintaining the leaflets in the coapted configuration after the catheter shaft has been removed from the patient's body, as now required by amended claim 20.

Because a single reference fails to teach or suggest each and every element of the claimed invention, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection be withdrawn and claim 20 and the claims depending therefrom be allowed.

Independent claim 67 has been similarly amended as claim 20 and therefore, for at least the reasons discussed above, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection be withdrawn and claim 67 and the claims depending therefrom be allowed.

Claim Rejections 35 U.S.C. § 103

Claim 83 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuehn in view of U.S. Patent No. 6,269,819 to Oz et al. (Oz). Such rejection is traversed in part and overcome in part for at least the following reasons.

Claim 82 includes the limitations of independent base claim 67 which recites in part a pair of articulating arms coupled together near the distal end of the flexible shaft and being moveable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together and to positions therebetween. As previously discussed above, Kuehn's graspers 440 in Fig. 20 grasp valve leaflets (col. 9, lines 49-50) and graspers 440 are drawn toward plunger 446 as shaft 456 is pulled (col. 9, lines 57-59). The graspers do not move closer together, they only move linearly along a slot. Therefore, the graspers 440 in Kuehn are linearly movable and Kuehn fails to teach or suggest that the graspers are movable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together.

Furthermore, Kuehn discloses moving plunger 446 to draw graspers 440, but the cited reference fails to teach or suggest a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms. Additionally, as discussed above, Kuehn's graspers are used to temporarily grasp the valve leaflets until they can be fastened together and the graspers are then removed from the patient's body. Kuehn therefore

also fails to teach or suggest implantation of the articulating arms in the patient's body to maintain the leaflets in the coapted configuration after the flexible shaft has been removed.

Nevertheless, in order to more clearly emphasize these differences, claim 67 has been amended to recite an apparatus for repairing a valve in a patient's body, the valve having a plurality of moveable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising:

 a flexible shaft having a proximal end and a distal end;
 a pair of articulating arms coupled together near the distal end of the flexible shaft, forming an angle therebetween and being moveable from an open position in which portions of the articulating arms are spaced apart at a first angle, to a closed position in which the portions of the pair of articulating arms are closer together at a second angle less than the first angle and to positions therebetween, the pair of articulating arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other;

 a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms so as to vary the angle; and

 a pair of superior elements movably coupled, the superior elements configured to engage the superior surfaces whereby the leaflets may be engaged between the articulating arms and the superior elements,

 wherein the pair of articulating arms and superior elements are moved independently of one another and can be closed to engage the leaflets and thereafter be opened to allow release and recapture of the leaflets prior to implantation of the pair of articulating arms in the patient's body while maintaining the leaflets in the coapted configuration after the flexible shaft has been removed from the patient's body.

Support for this amendment may be found in Figs. 86 and 87A-87C along with the corresponding detailed description as filed, therefore no new matter has been added.

Claim 67 now recites in part a pair of articulating arms coupled together near the distal end of the flexible shaft, forming an angle therebetween and being moveable from an open

position in which portions of the articulating arms are spaced apart at a first angle, to a closed position in which the portions of the pair of articulating arms are closer together at a second angle less than the first angle and to positions therebetween. As previously discussed, the graspers 440 in Fig. 20 of Kuehn move linearly along a slot and therefore graspers 440 are not movable to a closed position in which the portions of the pair of articulating arms are closer together at a second angle less than the first angle, nor do graspers 440 move to positions therebetween, as required by claim 67.

Claim 67 also now recites in part a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms so as to vary the angle. Again, Kuehn's graspers 440 move linearly and thus Kuehn fails to teach or suggest a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms so as to vary the angle.

Additionally, claim 67 now recites in part that the pair of articulating arms and superior elements are moved independently of one another and can be closed to engage the leaflets and thereafter be opened to allow release and recapture of the leaflets prior to implantation of the pair of articulating arms in the patient's body while maintaining the leaflets in the coapted configuration after the flexible shaft has been removed from the patient's body. Kuehn clearly indicates that graspers 440 are used to grasp the valve leaflets until they can be fastened together and then graspers are withdrawn. Graspers 440 are therefore not implanted into the patient's body after the flexible shaft has been removed from the patient's body.

Oz fails to provide the elements missing from Kuehn. Oz discloses an apparatus for the repair of a cardiovascular valve comprising a grasper having articulating arms that are capable of grabbing and coapting the valve leaflets (Abstract). Once the leaflets are coapted, they are fastened together with a fastener that is detachably coupled to the grasper arms (Figs. 10-13, 18-20). The fastener is left in the patient but the grasper is removed from the patient and thus the articulating arms in Oz do not remain in the patient. Since the grasper in Oz is not left in the patient, the cited reference fails to teach or suggest that the pair of articulating arms and superior elements are moved independently of one another and can be closed to engage the

leaflets and thereafter be opened to allow release and recapture of the leaflets prior to implantation of the pair of articulating arms in the patient's body while maintaining the leaflets in the coapted configuration after the flexible shaft has been removed from the patient's body, as required by claim 67.

Because the cited references alone or in combination fail to disclose each and every element of claim 83, *prima facie* obviousness under 35 U.S.C. § 103(a) cannot be established. Applicants therefore request that the § 103(a) rejection be withdrawn and claim 83 be allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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